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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,646	10/29/2003	Peter Aage Frischauf	036249-5001	4079

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MORGAN, LEWIS & BOCKIUS LLP
1111 Pennsylvania Avenue, N.W.
Washington, DC 20004

EXAMINER	
WALLENHORST, MAUREEN	

ART UNIT	PAPER NUMBER
1743	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/695,646	FRISCHAUF ET AL.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-35 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 10/29/03, 6/23/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

2. Claims 1-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite since it is not clear how and when the two steps comprising a calibration and quality control cycle have to be repeated. In other words, do the calibration and quality control steps of a cycle have to be repeated immediately after a previous cycle has been completed, or can a test sample be analyzed by the sensor after a first cycle has been completed but before a second cycle is performed/ repeated? See this same problem in claim 18.

Claim 11 is indefinite since it is not clear how and when the second calibration of the sensor is performed. In other words, does the second calibration of the sensor have to be performed immediately after the quality control step, or can a test sample be analyzed with the sensor after the quality control step but before the second calibration step?

Claim 26 is indefinite since it is not clear how and when the multiple calibration and quality control cycles are performed. In other words, do these cycles have to be performed sequentially one after another, or can the sensor analyze a test sample after a first cycle has been performed but before a second cycle is started?

Claim 35 is indefinite since it is an exact duplicate of claim 9. Both claims 35 and claim 9 depend from claim 1 and recite that the parameter is a blood parameter. Claim 35 should depend from claim 26.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 11-12, 14 and 16-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Enzer et al (US Patent 4,871,439, submitted in the Information Disclosure Statement filed on June 23, 2004).

Enzer et al teach of a method and apparatus for measuring certain parameters in a body fluid such as a blood sample. The apparatus comprises a disposable cartridge or cassette containing sensors for different parameters. The sensors comprise electrodes, and upon insertion of the cartridge into a blood chemistry analysis machine, the electrodes of the sensors connect to an electrode interface on the analysis machine, which selects one of the electrical signals from the sensors and passes the signal to a microprocessor in the machine where it is converted from analog to digital form suitable for analysis, storage and display. The cartridge contains therein containers 14 and 16 for calibration solutions A and B. The calibration solutions A and B

contain different levels of different parameters therein such as different levels of electrolytes. See lines 50-68 in column 5 and lines 1-51 of column 6 in Enzer et al. The compositions of the two calibrating solutions are chosen so that for each of the parameters measured by the system, a pair of values is obtained that are spaced over the range of permissible values that are measured by the system, thus providing a balanced 2-point calibration of the instrument. In a method of using the apparatus, Enzer et al teach that first, a cartridge containing sensors and calibration solutions therein is inserted into a blood chemistry analyzer. A valve 18 in the cartridge is then controlled to direct the calibration solution A into the sensor assembly so that it entirely fills up the flow channel. After a predetermined time for stabilization, measurements of the various potentials and currents are made and processed by the controller. Next, a predetermined quantity of calibration solution B is pumped into and through the sensor card, while during a certain dwell time, measurements are made. A blood sample is then pumped into the cartridge while analogous measurements are made, and based on the measurements of the blood sample and the stored calibration measurements, the controller generates blood gas/electrolyte values characteristic of the blood sample. Enzer et al teach that the process of calibration and blood analysis may be repeated a number of times either automatically or manually until all of the calibration solutions A and B in the containers 14 and 16 have been depleted. See lines 20-50 in column 15 and Figures 1 and 2 of Enzer et al.

With regards to claims 11-12, 14 and 16-17, the calibration solution A taught by Enzer et al can be considered a first calibration solution of the sensors in the cartridge since it comprises a reference composition containing a certain parameter level of different parameters. The calibration solution B taught by Enzer et al can be considered a quality control solution for the

sensors in the cartridge since it contains another reference composition containing certain parameter levels of parameters that are different than the parameter levels used in calibration reference solution A. In addition, calibration solution B is applied to the sensors in the cartridge after the sensors are first calibrated with calibration solution A. Therefore, the quality control of the sensors by calibration solution B is performed on the sensors "as calibrated". Since Enzer et al teach that the process of calibration of the sensors with solutions A and B can be repeated, and instant claim 11 does not specify when the second calibration of the sensor using the same reference materials as were used in the steps of performing the first calibration and quality control is performed (i.e. either immediately after the first cycle of calibration and quality control is performed or after a test blood sample is analyzed), the teaching of Enzer et al anticipates instant claims 11-12, 14 and 16-17.

With regards to apparatus claims 18-25, the apparatus taught by Enzer et al serves to anticipate these claims since it comprises one or more sensors sensitive to parameters in a test blood fluid, reference materials representing at least two different parameter levels of different parameters (i.e. blood gases, electrolytes) in the form of calibration solutions A and B, and a programmable device (i.e. a microcontroller) for controlling the functioning of the apparatus. Since apparatus claims are patentable only based upon the physical components which make up the apparatus and not by the functions or methods they perform, the limitations on lines 7-17 of claim 18 are not given any patentable weight. A recitation with respect to the manner a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the structural limitations of that claimed. See In re Yabnush, 477 F. 2d 1028, 168, USPQ 530 (CCPA 1971).

6. Claims 1 and 26 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action since none of the prior art of record teaches or fairly suggests a method of performing calibration and quality control of a sensor for determining a parameter in a test fluid in which a calibration and quality control cycle is repeated, wherein each cycle comprises the steps of performing at least one calibration of the sensor using a reference material representing a parameter level of the parameter, and performing at least one quality control of the sensor, as calibrated, using another reference material representing another different parameter level of the parameter than used in the calibration step, and wherein in one cycle the reference material used in the quality control step is used in the calibration step of another cycle.

7. Claims 2-10, 13, 15 and 27-35 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims for the same reasons as set forth above.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Kimball et al who teach of a calibration system for sensors located in a physiologic line, wherein both calibration and quality control of the sensors is performed periodically.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

June 14, 2007

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP [redacted] 1700